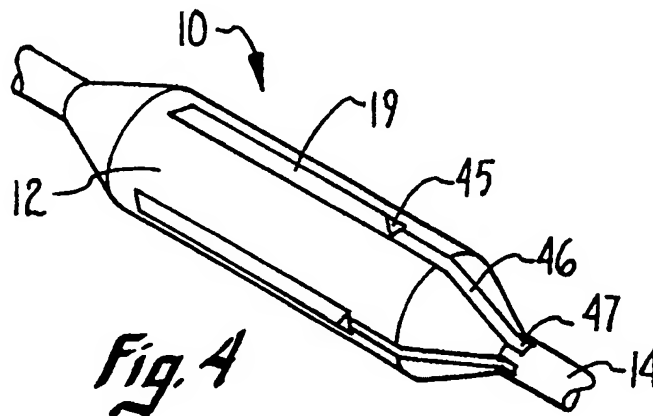


### REMARKS

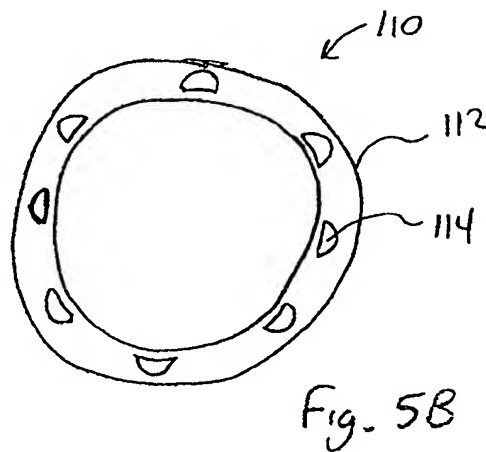
In response to the advisory action mailed March 29, 2005, Applicants amended claims 1, 14, 36, and 43, and canceled claims 5 and 35. Claims 37-42 and 44-72 were previously withdrawn. Thus, claims 1-4, 6-18, 20-34, 36, and 73-81 are presented for examination.

Claims 1-18, 20-36, and 73-81 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vigil (U.S. Patent No. 5,336,234) in view of Grayzel (U.S. Patent Publication No. 2002/0010489). Applicants' claims, as amended, cover a medical device including a balloon having a first material and a second material (or striped portion) encapsulated by the first material and a cutting element carried by (or attached to) the balloon over the second material (or striped portion). Grayzel and Vigil, taken alone and in combination, fail to disclose or suggest each of the above-noted elements of Applicants' claims.



Vigil discloses a balloon catheter having oscillatable arthertomes mounted along the outer surface of the balloon. *See, e.g.*, Col. 1, lines 15-19. Vigil's Figure 4 above, for example, illustrates a catheter 10 that can be used to impart oscillatory motion to arthertomes 19 without relying on the stiffness of the thin outer wall of a balloon 12, which can provide a dampening effect. *See, e.g.*, Col. 4, line 62 through col. 5, line 4. Arthertomes 19 are attached to a catheter tube 14 by strips 46. *See, e.g.*, Col. 4, lines 53-55. During use, oscillatory motion can be

transmitted to artherotomes 19 via catheter tube 14. *See, e.g.*, Col 4, lines 4-13. Vigil notes that this arrangement can be useful for applications requiring the imposition of more force or higher frequencies in the oscillatory movement motion of artherotomes 19 than is possible in view of the dampening effect of the thin wall of balloon 12. *See, e.g.*, Col. 4, line 62 through col. 5, line 4.



Grayzel discloses a balloon catheter having a balloon with stiffening members that aid in uniform expansion of the balloon at a target site in a lumen in the human body. *See, e.g.*, ¶ 0013. Referring to Grayzel's Fig. 5B above, Grayzel describes a device 110 including a balloon 112 with embedded stiffening members 114. *See* ¶ 0070. During use, the stiffening members act to focus the expansion force of the balloon at occlusions in a lumen contacted by the stiffening members. *See, e.g.*, ¶ 0053.

The Examiner contended in the advisory action that because Vigil explains that the stiffness of a thin wall balloon is insufficient to impart oscillatory motion to atherotomes attached thereto and because Grayzel describes a configuration for reinforcing balloon walls, a person of ordinary skill in the art would have been motivated to provide the thin wall balloon of Vigil with the reinforcing configuration described in Grayzel. The Examiner's position was explained in greater detail in the office action mailed January 20, 2006, which noted that a person of ordinary skill in the art would have been motivated based on the disclosures of Vigil and Grayzel to embed Vigil's strips 46 within the material of Vigil's balloon. The Examiner

further contended in the office action mailed January 20, 2006 that the resulting device would perform equally well as compared to the device illustrated in Vigil's Figure 4 (discussed above). However, a person of ordinary skill in the art would not have been motivated to combine the teachings of Vigil and Grayzel in such a way as to arrive at Applicants' claims, namely: a medical device including a balloon having a first material and a second material (or striped portion) encapsulated by the first material and a cutting element carried by (or attached to) the balloon over the second material (or striped portion).

The Examiner's assumption that the above-described device resulting from the combination of the teachings of Vigil and Grayzel would perform as well as the device disclosed in Vigil is simply incorrect. In the device suggested by the Examiner, Vigil's arthertomes 19 would be attached directly to the material of the thin wall balloon, rather than to stiff strips extending along the outer surface of the thin wall balloon. Consequently, to oscillate arthertomes 19, oscillatory motion would have to be transferred through the balloon material. Transferring the oscillatory motion through the balloon material would cause the undesirable effect of dampening the oscillatory motion. This is in stark contrast to the device illustrated in Vigil's Figure 4 which is designed to impart oscillatory motion to the atherotomes without relying on the stiffness of the thin outer wall of the balloon in order to avoid an undesirable dampening effect caused by the balloon material. Col. 4, line 62 – col. 5, line 4. Delivering oscillatory motion to the arthertomes in the device suggested by the Examiner would require that the oscillatory motion be transferred through the balloon material. Therefore, the device suggested by the Examiner would, in fact, have a negative impact on the oscillatory motion of the arthertomes. Consequently, not only would a person of ordinary skill in the art not have been motivated to make the combination suggested by the Examiner, a person of ordinary skill in the art would have been discouraged by the disclosure of Vigil from making such a combination.

There are two other general ways in which Grayzel's stiffening configuration could be applied to Vigil's thin wall balloon, as suggested by the Examiner. First, as shown in Figure 1<sup>1</sup> below, Grayzel's stiffening members 114 could be embedded within the balloon wall of the

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<sup>1</sup> Figure 1 was created by Applicants to facilitate discussion.

device illustrated in Vigil's Figure 4 (above) such that Vigil's strips 46 and arthertomes 19 are positioned over the embedded stiffening members 114. Second, as shown in Figure 2<sup>2</sup> below, Grayzel's stiffening members 114 could be embedded within the balloon wall of the device illustrated in Vigil's Figure 4 (above) such that Vigil's strips 46 and arthertomes 19 are positioned over a region the balloon that is free of the embedded stiffening members 114.

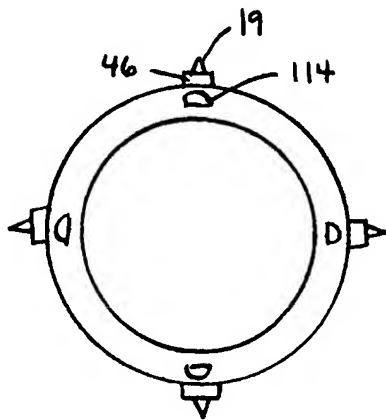


FIG. 1

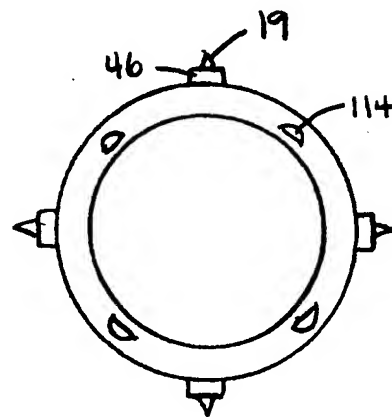


FIG. 2

A person of ordinary skill in the art would not have been motivated to combine the teachings of Vigil and Grayzel to produce the device shown in Figure 1. In fact, a person of ordinary skill in the art would likely have been discouraged from making such a combination. Referring to Figure 1, both strips 46 and stiffening members 114 would function to stiffen the regions of the balloon in/on which they are positioned. Such an arrangement would at the very least be redundant and would likely result in an overly stiffened region of the balloon, thereby promoting non-uniform expansion as opposed to uniform expansion of the balloon, a primary goal of Grayzel.

Applicants need not address the device of Figure 2 in great detail because Applicants' claims, as amended, require that the cutting element be over the second material (or striped portion) of the balloon. Even if a person of ordinary skill in the art would have been motivated

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<sup>2</sup> See FN 1.

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to combine the teachings of Vigil and Grayzel to achieve the device of Figure 2, which Applicants' do not concede, the device of Figure 2 does not include each and every element of Applicants' claims.

For at least the reasons discussed above, Applicants request reconsideration and withdrawal of the rejection of Applicants' claims.

No fees are believed due at this time. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: April 18, 2006

  
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